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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,829	09/09/2003	Nikolai M. Krivitski	86017.000037	1750

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EXAMINER	
PANI, JOHN	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
07/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/657,829	KRIVITSKI ET AL.	
	Examiner	Art Unit	
	JOHN PANI	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16-22 and 28-30* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16-20 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/18/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/18/2010 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 6,089,103 to Smith ("Smith '103").

4. Smith '103 discloses:

In reference to Claim 29

A method of measuring a blood flow rate, the method comprising: passing a guide wire (2) through an indicator lumen (interior of catheter body) in an elongate catheter body (14) to pass a portion of the guide wire through a terminal port ("distal

opening") of the indicator lumen; passing the indicator through the indicator lumen to pass from the elongate catheter body through the terminal port and an injection port (16) intermediate the terminal port and a proximal end of the catheter body (see col. 5 lines 10-20); sensing the indicator intermediate the terminal port and the injection port along a direction of blood flow (see Fig. 3, the sensor 4 is located intermediate the terminal port and the injection port at least in a direction orthogonal to the longitudinal axis of the catheter 14; note that the sensing occurs along a direction of blood flow because the sensor extends along the direction of blood flow); and calculating the blood flow rate based on passage of the indicator through the terminal port (col. 4 lines 20-40; note that because the transit time is used to calculate the flow rate, and the passage of indicator through the terminal port is used to determine the transit time, the blood flow rate is calculated a as a function of its passage through the terminal port).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 14, 17, 19, 20, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,089,103 to Smith ("Smith '103") US in view of Pat. No. 6,343,514 to Smith ("Smith '514").

In reference to Claim 14

Smith ‘103 discloses a method of measuring a blood flow rate, the method comprising: passing a guide wire (2) through an indicator lumen (interior of catheter body) in an elongate catheter body (14) to pass a portion of the guide wire through a terminal port (“distal opening”) of the indicator lumen; passing the indicator through the indicator lumen to pass from the elongate catheter body through the terminal port and an injection port (16) intermediate the terminal port and a proximal end of the catheter body (see col. 5 lines 10-20); distinguishing an amount of the indicator passing through the terminal port from an amount of the indicator passing through the injection port (note that by causing some of the indicator to be expelled through the side injection ports and some through the terminal port, the method "distinguishes" between these amounts at least in the sense that the amounts are directed in different manners) and calculating the blood flow rate (see col. 5 line 60 – col. 6 line 1). However, it is unclear whether Smith '103 calculates the blood flow rate as a function of the amount of indicator passing through the terminal port. Smith ‘103 does however note that the flow parameter is calculated similarly to the method found in WO 97/27802, of which Smith '514 is a continuation (col. 5 lines 60-65).

Smith ‘514 discloses using the total volume of injected indicator to calculate the blood flow rate (see col. 7 lines 20-44). It would have been obvious to one having ordinary skill in the art at the time of the invention to have similarly used the total volume of injected indicator to determine the blood flow rate, as Smith ‘103 explicitly states that this method “is suitable for the determination of the so called Coronary Fractional

Reserve (CRF)" (col. 5 lines 60-63), and Smith '103 uses the blood flow rate to calculate CFR.

Because the total volume of indicator (i.e. the amount of indicator) is used to calculate the blood flow rate, the blood flow rate is calculated as a function of the amount of the total indicator. Because the amount of the total indicator is a function of the amount of indicator passing through the side ports and the terminal ports, the blood flow rate is likewise calculated as a function of the amount of the indicator passing through the terminal port.

In reference to Claim 17

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses passing the indicator through the indicator lumen to contact a portion of the guide wire (col. 4 lines 34-37).

In reference to Claim 19

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses calculating the blood flow rate comprises compensating for a volume of the indicator passing through the terminal port (by using a total volume).

In reference to Claim 20

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses the calculated blood flow rate is described by a relationship $Q = (k(T_b-T_i)*V(1-a))/S$, where Q is the calculated blood flow rate, k is a coefficient related to thermal capacity of a measured flow and the indicator, T_b is a

temperature of a measured flow prior to injection of the indicator, T_i is a temperature of the indicator prior to entering the measured flow, V is a volume of the indicator, S is an area under a temperature versus time curve resulting from a mixing of the indicator and a is a portion of the indicator passing through the terminal port, the calculated blood flow rate being a value provided by an appropriate selection of k, T_b, T_i, V, S, and a. (Note: This limitation has been interpreted to essentially require that for the calculated flow value, the flow value calculated in claim 14 could be obtained by choosing appropriate values for the variables in the cited relationship. The "blood flow rate" calculated in claim 14 is essentially some numerical value, and any numerical value could be generated using the claimed relationship of claim 20 by selecting the appropriate combination of values for the parameters).

In reference to Claim 28

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses comprising sensing the indicator intermediate the terminal port and the injection port along a direction of blood flow (see Fig. 3, the sensor 4 is located intermediate the terminal port and the injection port at least in a direction orthogonal to the longitudinal axis of the catheter 14).

In reference to Claim 30

Smith '103 discloses a method of measuring a blood flow rate, the method comprising: passing a guide wire (2) through an indicator lumen (interior of catheter body) in an elongate catheter body (14) to pass a portion of the guide wire through a terminal port ("distal opening") of the indicator lumen; passing the indicator through the

indicator lumen to pass from the elongate catheter body through the terminal port and an injection port (16) intermediate the terminal port and a proximal end of the catheter body (see col. 5 lines 10-20); and calculating the blood flow rate (see col. 5 line 60 – col. 6 line 1). However, it is unclear whether Smith '103 calculates the blood flow rate as a function of a total volume of the indicator and a portion of the total volume passing through the terminal port. Smith ‘103 does however note that the flow parameter is calculated similarly to the method found in WO 97/27802, of which Smith '514 is a continuation (col. 5 lines 60-65).

Smith ‘514 discloses using the total volume of injected indicator to calculate the blood flow rate (see col. 7 lines 20-44). It would have been obvious to one having ordinary skill in the art at the time of the invention to have similarly used the total volume of injected indicator to determine the blood flow rate, as Smith ‘103 explicitly states that this method “is suitable for the determination of the so called Coronary Fractional Reserve (CRF)” (col. 5 lines 60-63), and Smith ‘103 uses the blood flow rate to calculate CFR.

Because the total volume of indicator (i.e. the amount of indicator) is used to calculate the blood flow rate, the blood flow rate is calculated as a function of the amount of the total indicator. Because the total volume of indicator is a function of the amount of indicator passing through the side ports and the terminal ports, the blood flow rate is being calculated both as a function of the total volume of the indicator and a portion of the total volume passing through the terminal port (because the total volume of indicator is itself a function of the portion of the total volume passing through the

terminal port; specifically, the total volume is fairly described as Vtotal = Vterminal + Vside) .

7. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith '103 in view of Smith '514 as applied to claim 14 above, and further in view of US Pat. No. 5,221,256 to Mahurkar ("Mahurkar").

In reference to Claims 16 and 18

Smith '103 in view of Smith '514 discloses the method of claim 14 (see above) and Smith '103 further discloses passing the guide wire through the indicator lumen to increase a flow of the indicator through the injection port (as its presence would increase flow through these compared with a situation in which it was not there) but does not explicitly teach a reduced cross sectional area of the indicator lumen. Mahurkar teaches (see Fig. 4) a catheter with a fluid injection lumen with multiple ports (21, 22). The injection lumen tapers and has a reduced cross-sectional area at its tip. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Smith '103 in view of Smith '514 by making the catheter with a similar tip and lumen configuration so that the distal tip would be more flexible and atraumatic as implicitly taught by Mahurkar.

Response to Arguments

8. Applicant's arguments, see pg. 6 last paragraph – pg. 7 first paragraph, with respect to claims 14, 20, and 29 have been fully considered and are persuasive. The

objection and rejections under 35 U.S.C. 112 second paragraph of 2/25/2010 has been withdrawn.

9. Applicant's arguments filed 6/4/2010 have been fully considered but they are not persuasive. In response to Applicants' assertion that "Smith does not disclose or suggest, among other things, distinguishing an amount of the indicator passing through the terminal port from an amount of the indicator passing through the injection port", the Examiner respectfully disagrees, because as noted above, the method of Smith '103, by causing these amounts to flow in different manners, "distinguishes" these amounts.

10. In response to Applicants' assertion that "Smith does not disclose or suggest, among other things, sensing the indicator intermediate the terminal port and the injection port along a direction of blood flow", the Examiner respectfully disagrees, and submits that the limitation "sensing the indicator intermediate the terminal port and the injection port along a direction of blood flow" is fairly interpreted to require sensing the indicator intermediate the terminal port and the injection port and sensing along a direction of blood flow (i.e. the claim does not require, as apparently argued by Applicant, that the *sensor* is located intermediate the terminal port and the injection port along the direction of the blood flow).

11. In response to Applicants' arguments that because "Smith does not distinguish the amount of saline expelled through the distal opening of its catheter from the amount of saline expelled through the side holes 16a, 16 in calculating its flow parameter", the Examiner notes that this is not claimed, and that as explained above, Smith '103

discloses "calculating the blood flow rate as a function of a total volume of the indicator and a portion of the total volume passing through the terminal port".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JP/ 6/30/10

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736